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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/560,322

09/12/2006

Birgit Baumgarten

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7590

09/09/2008

NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, INC.
400 TECHNOLOGY SQUARE
CAMBRIDGE, MA 02139

EXAMINER

LI, RUIXIANG

ART UNIT

PAPER NUMBER

1646

MAIL DATE

DELIVERY MODE

09/09/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,322	BAUMGARTEN ET AL.	
	Examiner	Art Unit	
	RUIXIANG LI	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-15 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1-4, 7, 8, and 9 (in part), drawn to a method to identify an agonist or antagonist of an isolated proton-sensing GPCR polypeptide.
- II. Claim 5, drawn to the use of an isolated polynucleotide in the development of a medicament for treatment of diseases and medical condition in which proton homeostasis is imbalanced.
- III. Claim 6, drawn to a method of prevention and/or treatment of diseases and medical conditions in which proton homeostasis is imbalanced, comprising administering to a subject in need thereof an effective amount of an antibody.
- IV. Claim 9 (in part), drawn to a method to identify compounds that stimulate or inhibit expression level of a polypeptide.
- V. Claims 10 and 12, drawn to a method of prevention and/or treatment of diseases and medical conditions in which proton homeostasis is imbalanced, comprising administering to a subject in need thereof an effective amount of an antagonist.
- VI. Claims 11 and 13, drawn to a method of prevention and/or treatment of diseases and medical conditions in which proton homeostasis is imbalanced, comprising administering to a subject in need thereof an effective amount of an agonist.

Art Unit: 1646

VII. Claims 14 and 15, drawn to a diagnostic kit comprising an antibody against a polypeptide.

2. The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature in Group I is a method to identify an agonist or antagonist of an isolated proton-sensing GPCR polypeptide.

The special technical feature in Group II is the use of an isolated polynucleotide in the development of a medicament for treatment of diseases and medical condition in which proton homeostasis is imbalanced.

The special technical feature in Group III is a method of prevention and/or treatment of diseases and medical conditions in which proton homeostasis is imbalanced, comprising administering to a subject in need thereof an effective amount of an antibody.

The special technical feature in Group IV is a method to identify compounds that stimulate or inhibit expression level of a polypeptide.

The special technical feature in Group V is a method of prevention and/or treatment of diseases and medical conditions in which proton homeostasis is imbalanced, comprising administering to a subject in need thereof an effective amount of an antagonist.

The special technical feature in Group VI is a method of prevention and/or treatment of diseases and medical conditions in which proton homeostasis is imbalanced,

Art Unit: 1646

comprising administering to a subject in need thereof an effective amount of an agonist.

The special technical feature in Group VII is a diagnostic kit comprising an antibody against a polypeptide.

Accordingly, Groups I-VII are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept. Thus, unity of invention is lacking and restriction is appropriate.

3. Furthermore, this application contains claims directed to the numerous amino acid/nucleic acid sequences, as represented by SEQ ID NOS. Each amino acid/nucleic acid sequence represents an *additional* invention group. As evidenced by the database accession numbers recited in claims 2 and 5, the nucleic acid sequences that encode the proton-sensing GPCR polypeptide are well known in the prior art. Therefore, the technical feature linking these nucleic acid sequences that encode proton-sensing GPCR polypeptide does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Applicant is advised that a reply to this requirement must include an identification of an amino acid/ nucleic acid sequence that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. The

Art Unit: 1646

Examiner notes that this is not a species election requirement; rather it sets forth additional invention groups.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (I).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

Application/Control Number: 10/560,322

Page 6

Art Unit: 1646

have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

/Ruixiang Li/

Primary Examiner, Art Unit 1646

Ruixiang Li, Ph.D.

September 3, 2008